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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,675	08/22/2003	Peter T. O'Heeron	122182.00021	1017

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EXAMINER

FIDEI, DAVID

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,675

Applicant(s)

O'HEERON, PETER T.

Examiner

David T. Fidei

Art Unit

3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/12/04</u> . | 6) <input type="checkbox"/> Other: ____. |

Claim Construction

1. In analyzing applicant's invention as set out in the pending claims, the examiner sets forth the following to aid in understanding the application of the prior art herein. Claims are to be given their broadest reasonable during prosecution, see *In re Priest*, 582 F.2d 33, 37 199 USPQ 11, 15 (CCPA 1978), and limitations from the specification will not be read into the claims, see, e.g. *In re Prater*, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997), see MPEP 2106.

For example; since an obturator is defined as having a distal end shaped to cut/separate tissue, a proximal end shaped for grasping and a shaft therebetween, the combination of separate elements forming this construction can be considered as defining an obturator.

The term integral is used in claim 2. However, The term integral was held not to be limited to a fabrication of the parts from a single piece of metal, but was inclusive of other means for maintaining the parts fixed together as a single unit. *In re Larson et al.*, 340 F.2d 965, 144 U.S.P.Q. 347 (C.C.P.A. 1965). "Integral" is sufficiently broad to embrace constructions united by such means as fastening and welding. *In re Hotte*, 475 F.2d 1009, 148 U.S.P.Q. 326 (C.C.P.A. 1973). Accordingly, a device is integral where the constituent parts are so combined so as to constitute a unitary whole.

The term disposable, claim 3, is considered a functionally valueless term. Anything can be considered disposable in that all you have to do is throw it away.

Cutting tips and separating tips are disclosed and claimed that provides no distinction of one over another. Broadly speaking a cutting tip can also be considered a tissue-separating tip since it can be used for this purpose.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 it is unclear what is meant by a shield-less obturator. How this distinguishes over other obturators or any other special meaning attached to the term. Said obturators in claims 3 and 4 have no antecedent basis.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Vidal et al (Patent no. 5,405,328). A medical kit is recited comprising at least one shield-less obturator for use in one or more trocars, said obturator having a distal or penetration end, a proximal or handling end and a shaft located between the two. A nominal package for enclosing the obturator is also recited.

Obturators for use with trocars are notoriously old and well known. Typically, the obturator has a distal end for cutting a proximal end with a handle and shaft therebetween. See Vidal et al, col. 3, lines 1-3. A package for an obturator is also not novel and shown in figure 16 of Vidal.

As to claim 2, the proximal end 202 and the distal end, any one of 210-215

As to claim 3, the obturators are considered disposable.

Art Unit: 3728

As to claim 4, a handle has already been described above.

As to claim 5, the distal end, defined by any of members 211-215 is shaped to cut and/or separate tissue.

As to claim 10, at least three obturators are shown in figure 16 and as many as seven obturators are shown in figure 15 where each tip can be combined with shaft 201.

As to claim 11, a blunt tip 213 is provided and tissue separating and cutting tips 211 and 212. Also figure 15 discloses a host of tip where the distinction between a cutting and tissue separating is not seen.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 6-9 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidal et al (Patent no. 5,405,328) as applied to claims 1-5, 10 and 11 above, and further in view of Johnson (Patent no. 5,118,297).

The difference between the claims 6, 12, 14, and Vidal et al resides in the handle member having at least one indicator. Johnson discloses that it is well recognized to provide obturators with raised indicators 20. Alternatively the proximal end 12 may be provided with an indicator 24A as shown in figure 6. To provide the obturator of Vidal with such an indicator would have been obvious to one of ordinary skill in the art for the reason of assisting the user in matching the obturator by conveying information about the obturator.

As to claims 7, 9 and 12, to employ printing, graphics, textual, pictorial messages, raised surfaces, indentations or any form of conveying a distinctive mark would have been obvious to one of ordinary skill in the art for the reason that the particular mark used is of no specific

Art Unit: 3728

criticality and is within the level of ordinary skill, long known to raised surfaces (as in Braille) as an indicia means.

As to claim 8, a blunt tip 213 is provided and tissue separating and cutting tips 211 and 212. Also figure 15 discloses a host of tip where the distinction between a cutting and tissue separating is not seen.

Priority

8. It is noted that this application claims benefit to a copending Application No. NOT GIVEN, filed August 1, 2003. The reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). Also, the current status of all nonprovisional parent applications referenced should be included.

Since the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c).

In view of the foregoing applicant has not perfected their claim for priority in a timely manner.

A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was

Art Unit: 3728

unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

Information Disclosure Statement

9. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

10. The information disclosure statement filed 10/12/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

REPLY BY APPLICANT OR PATENT OWNER TO THIS OFFICE ACTION

11. "In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to every ground of objection and rejection in this Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. The applicant's or patent owner's reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section.

The reply must be reduced to writing (emphasis added)", see 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

Art Unit: 3728

Pointing out specific distinctions means clearly indicating in the written response what features/elements or distinctions have been added to the claim/claims, where support is found in the specification for such recitations and how these features are not shown, taught, obvious or inherent in the prior a

If no amendments are made to claims as applicant or patent owner believes the claims are patentable without further modification, the reply must distinctly and specifically point out the supposed errors in the examiner's action and must respond to every ground of objection and rejection in the prior Office Action in the same vain as given above, 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.


The examiner also points out, due to the change in practice as affecting final rejections, older decisions on questions of prematurity of final rejection or admission of subsequent amendments do not necessarily reflect present practice. "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c)" (emphasis mine), see MPEP 706.07(a).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fidei whose telephone number is (571) 272-4553. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562.

Art Unit: 3728

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David T. Fidei
Primary Examiner
Art Unit 3728

dtf
January 7, 2005